IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ERIC L. JEFFRIES,	)	**CASE NO. C-1-02-351**
	:	
Plaintiff,	)	**JUDGE BECKWITH**
	:	
v.	)	
	:	
CENTRE LIFE INSURANCE CO.,	)	
	:	
Defendant.	)	

PLAINTIFF'S MEMORANDUM OPPOSING DEFENDANT'S
***DAUBERT* MOTION AND MEMORANDUM REGARDING PET/SPECT TESTIMONY**

This Court must reject defendant's request that the Court exclude from the trial of this matter objective, tangible evidence that Mr. Jeffries has an organic brain malady: testimony concerning the PET and SPECT scans.

Physicians and lay persons routinely use thermometers to measure body temperature. Evidence of an elevated body temperature, however, is not "diagnostic" of any illness *per se:* evidence of an elevated body temperature does not, for example, necessarily result in a diagnosis of pneumonia. Rather, a thermometer is a diagnostic tool and its display of an elevated temperature, when combined with other facts, events, findings, and science, assists a physician to gather an overall picture of the patient and develop a differential diagnosis of, in some cases, pneumonia.

Similarly, like a thermometer, PET and SPECT technology is now widely used by physicians to assist them in developing differential diagnosis. In this case, plaintiff's experts use the undisputed abnormal PET and SPECT scans, together with all other available evidence,

to help them develop the differential diagnosis that Mr. Jeffries has myalgic encephalomyelitis, also known as chronic fatigue syndrome ("ME/CFS").

It is undisputed that the PET and SPECT scans tangibly exhibit an organic insult to Mr. Jeffries' brain. (*See, Exhibit 1, filed separately, PET and SPECT Images*). This is the reason defendant desires desperately for the Court to exclude them from the trial. But just as evidence that Mr. Jeffries experienced a fever, arthralgias, myalgias, or cognitive decline following the vaccine should not and will not be excluded from the trial of this case, this Court should not exclude the PET and SPECT scans from the trial of the case. This is why many other Courts have allowed evidence of PET and SPECT scans.

I. Background.

In June 1997, Mr. Jeffries received a hepatitis B vaccination, during a period of time when he otherwise had an acute illness. Mr. Jeffries developed a lump at the site of his shot, which was later surgically removed.

Immediately after receiving the vaccination, Mr. Jeffries complained to his physician of failing health, including, *inter alia*, severe muscle pain, joint pain, cognitive difficulties, and fatigue. Mr. Jeffries' treating physician contacted the vaccine manufacturer who advised that Mr. Jeffries was suffering from an allergic reaction to the vaccine.

Over the next several months, Mr. Jeffries' battled his illness, but it progressively worsened. As defendant's experts concede, based on their own testing of Mr. Jeffries, his cognitive functioning has substantially deteriorated since the time he received the vaccination. And in 1998, Mr. Jeffries' chronic illness prevented him from continuing in his occupation.

The PET and SPECT scans that defendant desires to exclude offer objective evidence of Mr. Jeffries' brain abnormalities, which have led to Mr. Jeffries' cognitive deterioration. These abnormalities are consistent with the diagnosis of the medical illness diagnosed by plaintiff's experts. According to plaintiff's experts these scans display a man who could not have possibly performed Mr. Jeffries' occupation. As a result, Mr. Jeffries could not have possibly had these abnormalities before receiving the hepatitis B vaccination.

II. Framework Of Legal Analysis.

Applying FRE 702 and ***Daubert v. Merrell Dow Pharmaceuticals***, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993), this Court should deny defendant's motion. FRE 702 permits opinion testimony by experts as to matters amounting to "scientific . . . knowledge" which will "assist the trier of fact to understand the evidence or to determine a fact in issue." Here, as required by FRE 702:

(i) The use of the abnormal PET and SPECT scans by Mr. Jeffries' experts to render their conclusions is based upon sufficient facts/data; and

(ii) The testimony is the product of reliable principles and methods applied reliably to the facts of this case.

The Supreme Court in ***Daubert*** stated that "of course it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Id., at 590*. In order "to qualify as 'scientific knowledge' an inference or assertion must be derived by the scientific method [and] proposed testimony must be supported by appropriate validation - i.e., 'good grounds,' based on what is known." *Id*.[1] "Nothing in the text of this Rule establishes

[1] The principle thrust of ***Daubert*** was to abolish the earlier established ***Frye v. Untied States*** 293 F. 1013 (D.C. 1923) rule, which held that "the thing from which [an expert's deduction] is made

'general acceptance' as an absolute prerequisite to admissibility . . . and a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules." *Id., at 588.*

Accordingly, the Supreme Court concluded that the "austere [general acceptance] standard, [which is] absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials." *Id. at 589.*

After abolishing ***Frye***, the Supreme Court noted that the trial court must preliminarily assess "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Id. at 592-593.* The Supreme Court left it to federal judges "to undertake this review . . . we do not presume to set out a definitive checklist or test." *Id.*

Having established this framework, the Supreme Court noted that the following considerations would ordinarily be pertinent "in determining whether a theory or technique is scientific knowledge that will assist the trier of fact:"

- Whether it can be tested;
- Whether the theory or technique has been subjected to peer review and publication ("in some instances well-grounded but innovative theories will not have been published . . . [accordingly] the fact of publication (or lack thereof) in a peer reviewed journal will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised") *Id. at 593*;
- In "the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error;"

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must be sufficiently established to have gained general acceptance in the particular field in which it belongs." ***Daubert*** 509 U.S. at 586-587.

- The degree of acceptance within the scientific community. Although the Supreme Court abolished the "general acceptance" standard from ***Frye***, the Court stated that it can "have a bearing:" a "reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." *Id. at 594, citation omitted.*

In conclusion the Supreme Court stated that "the inquiry envisioned by Rule 702 is, we emphasize, a flexible one." *Id. at 594.*[2] The "scientific validity . . . of the principles that underlie a proposed submission" is the focus. *Id. at 595.* Experts pass ***Daubert*** muster based "solely on principles and methodology, not on the conclusions that they generate." *Id.*

Here the scientific reasoning and methodology underlying the use of the abnormal PET and SPECT scans in rendering a conclusion is scientifically valid and has properly been applied to the facts in issue. Accordingly, defendant's motion should be denied.

III. A Review of PET and SPECT Scan Technology.

Positron Emission Tomography, otherwise known as PET, is a measure of brain function or metabolism.[3] In a PET scan of the brain, a patient is injected with glucose labeled with radiopharmaceuticals tracers. The brain burns glucose as fuel, so the glucose goes to where the brain is working. The glucose produces radiation giving off gamma ray signals.

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[2] In ***Kumho Tire Co. v. Carmichael*** 526 U.S. 137, 143 L. Ed. 2d 238, 119 S. Ct. 1167 (1999), the Supreme Court clarified that whether the factors set forth in ***Daubert*** are reasonable measures of reliability in a particular case "is a matter that the law grants the trial judge broad latitude to determine . . . [the trial judge has] considerable leeway in deciding . . . how to go about determining whether particular expert testimony is reliable." *Id. at 141, 152.*

[3] Positron emission tomography (PET) is defined as "creation of tomographic images revealing certain biochemical properties of tissue by computer analysis of positrons emitted when radioactively tagged substances are incorporated into the tissue." Stedman's Medical Dictionary 1842 (27th ed. 2000).

As the patient lies on a table passing through a circular gamma ray scanner, PET measures the amount of physiological function in terms of glucose metabolism, and a computer reassembles the signals into color-coded images. If those parts of the brain are healthy and fully functional, they will consume a large quantity of the radioactively tagged glucose and appear as a bright orange or red color. Those parts of the brain that are damaged or simply inactive at the time of the scan will absorb little, if any, glucose, and will show up blue or purple on the finished scan. Yellows and greens are between these extremes. The colors have no intrinsic significance, but are merely a way of creating visual contrast to distinguish varying levels of metabolic activity in various parts of the brain.

Single Photon Emission Computerized Tomography or "SPECT" is similar in any ways to PET, but less precise.[4] SPECT essentially measures blood flow. A radioactive chemical is administered intravenously to the patient, but the radioactive chemical remains in the bloodstream and does not enter the brain. As a result, SPECT measures brain activity indirectly by gauging cerebral perfusion or the brain's vascular supply. Because damaged brain tissue normally shuts down its own blood supply, focal vascular defects on a SPECT scan may be used as evidence of brain damage.

The use of PET and SPECT in the medical community has soared within the last five years. In 1997, there were 73 PET scanning sites in the United States, concentrated primarily in the East and Midwest. Today, there are approximately 227 PET scan centers spread across the nation.

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[4] Single photon emission computed tomography (SPECT) is defined as "tomographic imaging of metabolic and physiologic functions in tissues, the image being formed by computer synthesis of photons of a single energy emitted by radionuclides administered in suitable form to the patient." Stedman's Medical Dictionary 1842 (27th ed. 2000).

The clinical applications for PET and SPECT have continued to expand within the fields of neurology and psychiatry. PET and SPECT imaging is used to diagnose and treat epilepsy, dementias and movement disorders (such as Parkinson's Disease, Huntington's Disease and Tourette Syndrome). These technologies are used in a variety of brain research applications, as in, for example, pinpointing the area of the brain responsible for ADD/ADHD in children. All of the major pharmaceutical drug manufacturers use them when applying for FDA approval of a new drug application, to show how the drug affects the metabolism and function of the human brain.

Another great stride in these technologies, particularly PET, has been the extension into the areas of cardiology and oncology. By measuring blood flow and metabolic rate within the heart, PET scans can identify the areas of decreased blood flow caused by blockages and differentiate muscle damage from living muscle. Because PET scanning can detect functional changes in cancerous cells observable structural changes occur in the tissue, PET scanning has proved to be an invaluable tool in the early detection of cancer. Oncologists rely on PET scanning also to determine the spread of cancer, whether a tumor is responding to a given course of treatment, and if a patient is free of cancer following the treatment.

PET has been an established scientific methodology within the relevant medical community for now well over a decade. An abundance of published medical and scientific literature now exists on the subject of PET and SPECT, both directly and tangentially in connection with the clinical uses of PET and SPECT, as well as their use in research into disease processes and their treatments.

Dr. Frey, the expert relied upon by the defendant to argue against the introduction of this evidence, testified that PET scans have been around in "significant volume" in the United States since the early 1980s. (*See, Frey Depo., filed separately, p. 12, lines 11-12*). According to Dr. Frey:

> "Beginning in the mid to late 1980s it began to be clear that in certain specific clinical situations there might be diagnostic value to PET . . . in the early and mid 1990s the clinical diagnostic use of PET became apparent and obvious to the medical community and there began to emerge centers that offered PET for clinical purposes alone as opposed to a combined research and clinical setting and then very recently over the last two or three years there's been exponential increase in the number of sites providing clinical PET." *Id.*

Dr. Frey also acknowledged that there are numerous major medical centers around the world that are publishing regularly on the use of PET scans. Probably the only thing that has prevented even wider use of PET is the cost, since a machine costs over $1 million and the tests cost a patient $2,500 or more. (*Id., at 15*)

Dr. Frey is even of the opinion that PET scans can be used in and of themselves to diagnose some conditions, without any other information. (*Id., at 28-29*) Dr. Frey agreed that doctors often use tests and findings that are not, in and of themselves, diagnostic, but are helpful in establishing a differential diagnosis. He discussed the analogies of using temperature (fever) in a diagnosis, or the use of a spinal tap where albuminological disassociation is evidence that supports a diagnosis of Guillain Barre Syndrome (GBS), but is also consistent with other conditions. (*Id., at 30*). Doctors frequently use test results that support or do not support a particular differential diagnosis.

Dr. Frey's main complaint goes more to the weight that should be given this evidence. While he admits that he is not familiar with the studies of PET and SPECT scan results in

conditions such as chronic fatigue syndrome (CFS) or encephalomyelitis that are published in the medical literature (*Id., at 34*), he questions the statistical reliability of any such studies. (*Id., at 31-32*) Dr. Frey admits that he is not an expert in CFS and was not even aware of the fact that CFS is, in fact, myalgic encephalomyelitis, and has been recognized as such by the CDC for years. (*Id., at 36*)

Most importantly for this Court, Dr. Frey conceded that he has no criticisms about the technical methods used or the quality of the scans performed by Dr. Wu at the University of California – Irvine:

> Q. Now, going to the PET scan from University of California Irvine, can you comment on any criticisms of those?
>
> A: No, those PET scans look of very reasonable diagnostic quality. They'd be comparable to work we would perform here. (*Id.,* at 48)

While Dr. Frey had some questions about why the people who performed the SPECT scans in Montreal performed scans at two times, instead of just once (which he thought would have been adequate), he conceded that the scans were "of diagnostic quality" and "looked like SPECT scans we would perform in our unit in terms of overall appearance of the data." *Id.*

Dr. Frey did have criticisms of the quality of the SPECT scans performed by Dr. Pretorius, but Dr. Pretorius can best answer those questions at the hearing that is scheduled in this matter. It is important to note, however, that Dr. Pretorius' results are consistent with the findings on repeated testing at Montreal and UCI.

Of particular interest to this Court may be the fact that Dr. Frey and Dr. Wu have already appeared on opposite sides of a lawsuit involving the use of PET scans for assisting with the diagnosis of brain injury in railway workers exposed to solvents while degreasing

locomotives. This case apparently was in Federal Court in St. Louis in the mid-1990s, and the judge allowed the testimony of both doctors on this issue. Other courts have also allowed and even invited PET/SPECT evidence.[5]

IV Analysis.

As the Court stated in ***Daubert***, the test of reliability is "flexible," and ***Daubert's*** list of specific factors neither necessarily nor exclusively applies to all experts in every case. The "law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id. (emphasis original*).

As discussed in detail in plaintiff's opposition to defendant's hepatitis B causation ***Daubert*** Motion (*Doc. 131*), the medical plausibility that the hepatitis b vaccine may cause injury cannot be disputed. The purpose of a vaccine is to stimulate a recipient's immune system, which may overreact to the vaccine, causing the body to attack itself, causing overstimulation and an autoimmune illness and/or neurological damage.

Dr. Geier analyzed the VAERS Database in great detail and has performed epidemiology to show that hepatitis B vaccine is associated with a statistically significant increased relative

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[5] See, *e.g.*, ***Rhilinger v. Jancics, et al.,*** 1998 WL 1182058 (Mass. Super. 1998) (court rejected ***Daubert*** argument and allowed jury to consider the results of a SPECT test. The court noted that SPECT technology has been used by the medical community for at least 15 years and "there is no dispute that SPECT scans show abnormalities in brain function . . . neither is there a dispute that SPECT scans cannot conclusively establish the existence or non-existence of TSE in a patient. Plaintiff's experts do not opine that the SPECT scan does, in fact, establish the diagnosis. They merely assert that it is one of a constellation of diagnostic tools which they used and considered consistent with their conclusion that [plaintiff] suffers from TSE." The judge held that SPECT is "scientifically reliable;" ***Guilbeau v. W.W. Henry Co.***, 85 F.3d 1149 (5th Cir. 1996); ***Hose v. Chicago Northwestern Transportation Co.***, 70 F.3d 968 (8th Cir. 1995), (expert's testimony was limited to showing consistency with, as opposed to diagnostic proof of, manganese encephalopathy); ***In re Air Crash at Little Rock Arkansas***, 291 F.3d 503 (8th Cir. 2002)(the Eighth Circuit noted in its opinion that the plaintiff failed to have a PET or SPECT test performed to confirm the existence of a physical injury. Thus, the Eighth Circuit seemed to indicate that a PET or SPECT just might have proved the requisite physical injury from PTSD).

risk of the very symptoms that Mr. Jeffries has experienced: arthralgias, arthritis, joint disease, neuropathy, myelitis, neuritis, myalgias, vasculitis, and liver abnormalities, among others. *Id. at pp. 20-24.*[6]

In assessing Mr. Jeffries' SPECT scans, Dr. Hyde noted "changes . . . includ[ing] a vasculitis-like pattern of the Central Nervous System . . . this probably relates to a low-grade inflammatory reaction of the CNS arterial bed." Dr. Hyde further commented that a PET scan of Mr. Jeffries' brain: "showed a wide area of injuries in [Mr. Jeffries'] lower brain . . . [Mr. Jeffries] has really significant changes in that area of the brain . . . There's no way that prior to that immunization he could have done the kind of work that did with this kind of brain. He neither has the strength, the elasticity, the memory."

Dr. Poser reviewed results of Mr. Jeffries' SPECT scan. According to Dr. Poser, the SPECT scan "revealed a pattern consistent with changes seen in chronic fatigue syndrome, a marked increase of antimicrosomal antibodies, an increase of CD4/CD8 cell ratio, and a thyroid biopsy showing papillary carcinoma." Dr. Poser stated that it was his opinion that:

> "Mr. Jeffries gives . . . the classical history of chronic fatigue syndrome (CFS) . . . the temporal relationship . . . [of the illness] to the vaccination . . . is such as to strongly suggest a causal relationship . . . I have seen several cases of classical CFS immediately following, and almost certainly resulting, from [a hepatitis B] vaccination [and] I am impressed by the results of the SPECT and PET scans and by the changes in [Mr. Jeffries'] immune system." *Id.*

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[6] Defendant incorrectly argues in its motion that there is no evidence of any "scientific fit between [the opinions offered by Drs. Geier, Hyde, and Waisbren] and Mr. Jeffries' factual symptoms." As indicated in Dr. Geier's peer-reviewed work, this is not true: the principal symptoms from which Mr. Jeffries suffers are known to result from the hepatitis B vaccine, even the drug manufacturer's caution lists Mr. Jeffries' symptoms as potential adverse reactions.

Conclusion

Like the undisputed evidence of Mr. Jeffries' myalgias, arthralgias, and cognitive decline following the vaccine (and like a thermometer revealing an elevated body temperature), the undisputed abnormal PET and SPECT scans reveal a piece of the medical equation and is consistent with a brain malady and ME/CFS. These abnormal scans assist the physicians in rendering a differential diagnosis. For this reason, defendant's motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The foregoing was delivered, via fax and regular U.S. Mail William R. Ellis, Esq., Wood & Lamping LLP, 600 Vine Street, Suite 2500, Cincinnati, Ohio 45202, this 20th day of January, 2004.

/s Michael A. Roberts